## REMARKS

Claims 1-43 are pending in the present invention. No additional claims fee is believed to be due.

### Rejection Under 35 USC 103(a) Over Nakamura et al (US 6,045,847) in view of Marlett et al (US 6,287,609) or Colliopoulos (US 5,009,916)

The Examiner states that claims 1-43 are rejected under 35 USC § 103 as being unpatentable over Nakamura et al (US 6,045,847) in view of Marlett et al (US 6,287,609) or Colliopoulos (US 5,009,916). The Examiner states that Nakamura discloses a composition comprising a water-soluble hemicellulose, which is a polysaccharide containing xylose and arabinose which may be used in an emulsified state with fat or oil. Additionally, the Examiner states that when Nakamura is combined with the Marlett the ratio of xylose to arabinose is at least 3:1. Applicants respectfully traverse the Examiner's rejection on the basis of the comments below.

Applicants assert that the Examiner has failed to establish a *prima facie* case of obviousness. Nakamura and Marlett or Colliopoulos do not teach or suggest all of the claim limitations of Claims 1-59 and, therefore, do not establish a *prima facie* case of obviousness. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03 citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 citing *In reWilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

The Nakamura references discloses the use of a water-soluble hemicellulose that is derived from husks of oily seeds of soybean, palm, coconut, corn or cottonseed with the oil and protein removed, and lees from grains such as rice or wheat and roots such as beets with the starch or sugar removed. *See* Column 3, lines 44-51. Each of these fibers is water soluble and is rapidly broken down in the colon. Due to this fact, these fibers have no laxative effects on the bowel and are not effective at treating constipation and other disorders of the bowel. The psyllium seed husks derived polysaccharide particles of the present invention are not

readily broken down in the colon so they pass through the colon and aid in making the stool soft and easy to eliminate thereby aiding in treating constipation and other bowel disorders.

The Hawley's Condensed Chemical Dictionary Fourteenth Edition, defines "emulsion" as 1. "a stable mixture of two or more immiscible liquids held in suspension by small percentages of substances called emulsifiers." The Hawley's Condensed Chemical Dictionary Fourteenth Edition, defines "emulsifiers" as "a surface active agent." The Hawley's Condensed Chemical Dictionary Fourteenth Edition, defines "surface active agent" as "any compound that reduces surface tension when dissolved in water or water solutions, or that reduce interfacial tension between two liquids, or between a liquid and a solid."

In the present invention, compositions comprise a plurality of agglomerates or polysaccharide particles which are coated with at least one or more surrounding layers. The agglomerate may be joined to one or more surrounding layers, which surround the polysaccharide particle. Using the polysaccharide particle as an example, the polysaccharide particle may be joined to one or more surrounding layers, which surround the polysaccharide particle. As used in the present application, the terms "joined to," or the like means surrounding the agglomerate, or polysaccharide particle, or the like, in such a manner that the layer is contiguous with either the agglomerate or polysaccharide component itself, a preceding layer, or a succeeding layer. The layer may be "joined to" the agglomerate or polysaccharide component, a preceding layer, or a succeeding layer even though other matter (such as another preceding or succeeding layer) intervenes. Accordingly, a layer which is "joined to" the agglomerate or polysaccharide component need not actually be contiguous with such agglomerate or polysaccharide component. The agglomerate or polysaccharide particle, as applicable, is joined to the first surrounding layer which is a hydrophobic layer, preferably a continuous hydrophobic layer. The hydrophobic layer therefore comprises one or more materials, such that the hydrophobic layer is hydrophobic. Inclusion of an agglomerate comprising such a hydrophobic layer is particularly useful to inhibit the final agglomerate from absorbing water. These benefits are similarly achieved wherein the polysaccharide particle is coated with a surrounding layer which is a hydrophobic layer, preferably a continuous hydrophobic layer. When the hydrophobic layer is utilized, it is

found that a second surrounding layer which is a hydrophilic layer is additionally beneficial. Indeed, while the hydrophobic layer inhibits the absorption of water into the agglomerate or particle (as applicable), the hydrophilic layer is useful for further enhancing dispersion of the final agglomerate or particle in an aqueous liquid prior to administration. *See* pages 11-13.

Nakamura describes an emulsified composition and the present invention teaches and claims the agglomerate or particle are coated or surrounded with a layer or layers. Additionally, Nakamura fails to teach or suggests a polysaccharide component comprising xylose and arabinose, where the ratio of the xylose to the arabinose is at least about 3 : 1, a polysaccharide particle that comprises polysaccharide component comprising xylose and arabinose, where the ratio of the xylose to the arabinose is at least about 3 : 1, by weight, and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns as disclosed and claimed in the present invention.

The Examiner states that Marlett teaches the preparation of fractions obtained from psyllium seed husk that comprises xylose and arabinose. However, Marlett fails to teach or suggest a polysaccharide particle that comprises polysaccharide component comprising xylose and arabinose, where the ratio of the xylose to the arabinose is at least about 3: 1, by weight, and polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns as disclosed and claimed in the present invention. Additionally, Marlett fails to teach or suggest compositions comprise a plurality of agglomerates or polysaccharide particles which are coated or surrounded with at least one or more surrounding layers.

Nakamura and Marlett both fail to provide Applicants' essential polysaccharide particle that comprises polysaccharide component comprising xylose and arabinose, where the ratio of the xylose to the arabinose is at least about 3 : 1, by weight, and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns and compositions comprise a plurality of agglomerates or polysaccharide particles which are coated with at least one or more surrounding layers. Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Nakamura and Marlett, one would still fall short of the of Applicants' claimed invention

only to arrive at a water-soluble hemicellulose that are water soluble and are rapidly broken down in the colon that comprise xylose and arabinose. The combination of Nakamura and Marlett do not teach or suggest each and every element of Applicants' presently claimed invention. The polysaccharide particles of the present invention, therefore, cannot be rendered as obvious over the teachings of Nakamura in view of Marlett.

The Examiner states that Colliopoulos teaches a psyllium high fiber drink mix made by agglomerating a base comprising at least 5 to 99 weight percent psyllium mucilloid. However, the present invention is directed to certain fractions of psyllium seed husk. The psyllium high fiber in the Colliopoulos reference when it comes in contact with water would form a gelatinous mass and would exhibit very poor dispersability. The present invention comprises composition that contain certain fractions of psyllium seed husk with defined ratio of xylose and arabinose wherein the composition comprises particles that have a defined particle size, or agglomerates with defined particle size which are intended for dilution in an aqueous liquid and provide excellent mouth feel, excellent dispersion in an aqueous liquid and sedimentation. The present invention teaches the removal or fractioning off of the components which contribute to the unpleasant or unsafe qualities of the psyllium husk. Therefore, one of ordinary skill in the art would not be motivated to combine the teaching of Colliopoulos with Nakamura or Marlett since the teachings of Colliopoulos fail to teach or suggest the use of at least 5 to 99 weight percent of polysaccharide particles that are fractioned off of the psyllium seed husk.

The combination of Nakamura and Marlett or Colliopoulos does not teach or suggest each and every element of Applicants' presently claimed invention. The polysaccharide particles of the present invention, therefore, cannot be rendered as obvious over the teachings of Nakamura in view of Marlett or Colliopoulos. "Citing a reference that merely indicates that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." *See Ex parte Hiyamizu*, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). "The genius of invention is often a combination of known elements which in hindsight seems preordained. To prevent hindsight invalidation of patent claims, the law requires some 'teaching, suggestion, or reason' to

combine cited references." *See McGinley v. Franklin Sports, Inc.*, 262 F. 3d 1339, 60 USPQ2d 1001 (Fed. Cir. 2001). "Determinations of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit parameters." *See ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 48 USPQ2d 1321 (Fed. Cir. 1998). "There should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention." *In re Dembiczak* 175 F. 3d 994, 999 (Fed. Cir. 1999).

Accordingly, Claims 1-43 are novel and nonobvious over Nakamura et al (US 6,045,847) in view of Marlett et al (US 6,287,609) or Colliopoulos (US 5,009,916) and reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 USC 103(a) Over Nakamura et al (US 6,045,847) and Marlett et al (US 6,287,609) in view of Barbera (US 5,425,945)

The Examiner states that Claim 24 is rejected under 35 USC § 103 as being unpatentable over Nakamura et al (US 6,045,847) and Marlett et al (US 6,287,609) as applied to Claims 1-43 and in further view of Barbera (US 5,425,945). Applicants respectfully traverse this rejection based on the remarks contained herein.

Applicants assert that the arguments presented above regarding Nakamura and Marlett in traversing the § 103(a) rejection also apply to the present rejection. The references do not teach or suggest the essential polysaccharide particle that comprises polysaccharide component comprising xylose and arabinose, where the ratio of the xylose to the arabinose is at least about 3 : 1, by weight, and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns and compositions comprise a plurality of agglomerates or polysaccharide particles which are coated or surrounded with at least one or more surrounding layers.

The Examiner states that Example 1 in Barbera shows polysaccharide particles having the instantly claimed particle size. However, if one looks to Example 1 of the Barbera patent, Example 1 discloses a steam sanitized psyllium husks having a particle size of 98% minimum through 100 mesh screen. *See* Example 1, lines 24-27. Barbera fails to teach or

suggest a composition that contains certain fractions of psyllium seed husk with defined ratio of xylose and arabinose wherein the composition comprises polysaccharide particles that have a defined particle size, or agglomerates comprising polysaccharide particles with defined particle size.

Additionally, the Examiner states that Barbera evidences the fact that psyllium material as part of the composition improves the mixability and dispersibility of the composition in liquids. However, Babera, fails to teach or suggest anything about what a polysaccharide component comprising xylose and arabinose, where the ratio of the xylose to the arabinose is at least about 3:1, by weight, and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns would do in a liquid. Therefore, Babera fails to teach or suggest polysaccharide particle that comprises polysaccharide component comprising xylose and arabinose, where the ratio of the xylose to the arabinose is at least about 3:1, by weight, and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns.

The combination of Nakamura and Marlett or Babera does not teach or suggest each and every element of Applicants' presently claimed invention. The polysaccharide particles of the present invention, therefore, cannot be rendered as obvious over the teachings of Nakamura in view of Marlett or Babera. "Citing a reference that merely indicates that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." *See Ex parte Hiyamizu*, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). "The genius of invention is often a combination of known elements which in hindsight seems preordained. To prevent hindsight invalidation of patent claims, the law requires some 'teaching, suggestion, or reason' to combine cited references." *See McGinley v. Franklin Sports, Inc.*, 262 F. 3d 1339, 60 USPQ2d 1001 (Fed. Cir. 2001). "Determinations of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit parameters." *See ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 48 USPQ2d 1321 (Fed. Cir. 1998). "There should be something in the prior art or a convincing line of reasoning in the answer

suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention." *In re Dembiczak* 175 F. 3d 994, 999 (Fed. Cir. 1999).

Accordingly, Claim 24 is novel and nonobvious over Nakamura et al (US 6,045,847) in view of Marlett et al (US 6,287,609) view of Barbera (US 5,425,945) and reconsideration and withdrawal of the rejection is respectfully requested.

## CONCLUSION

In light of the remarks presented herein, Applicants respectfully submit Claims 1-43 are allowable over the cited references. Reconsideration and allowance are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicants' undersigned attorney for further discussion.

Respectfully Submitted,
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